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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,627	07/06/2001	Charles David Weaver	3035-4086US1	7563

23914 7590 11/28/2003

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/28/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,627

Applicant(s)

WEAVER ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-120 is/are pending in the application.
- 4a) Of the above claim(s) 32-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-31, in Paper No. 7 is acknowledged. Applicant believes that invention V and VI, can be searched simultaneously with invention I on the ground that both claim 98 (invention V) and claim 109 (invention VI) depend on claim 31 (invention I). Applicant's argument has been considered but appears not persuasive because the feature of high throughput, contacting cells with electrolyte solution and test agents in claim 98 is not required in invention I. Similarly, the feature of initiating cell process in claim 109 is not required in invention I. The requirement is still deemed proper and is therefore made ***FINAL***.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 8, "electrically tight" seals is vague and indefinite. It is unclear what constitutes "electrically tight" seals in this incidence.

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With respect to claim 11, line 3, the material Teflon®, should not be used in the claim language.

With respect to claim 26, it is a duplicate claim of claim 20. Applicant also needs to renumbered dependent claims accordingly if deciding to cancel this claim.

With respect to claim 27, line 4, “secreted by the cell” is vague and confusing. It is not clear whether the enzymes are secreted by the sample cells, or by another source of cells.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 6-9, 12-13, 20, 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Baumann et al. (US 6475760).

Banmmann et al. teach using an apparatus for measuring intracellular manipulations of a biological cell. (See Fig. 1) The apparatus comprises two layers wherein the first layer having non-conductive materials with plurality of pores in contacting cells, and the second layer comprises a non-porous layer in contact the cell support membrane. (See Figure 1 , 6, 8) The device has boundary walls to form sample chambers. (See Figure 8) Additionally, Baumann et al. teach measuring cellular electrical condition, e.g. electrical potentials, by coating the layers with glass, plastic. (Col. 3, line 4-12; Col. 9, line 37-44) Furthermore, Baumann et al. teach permeabilizing cell membrane with Triton® and coating the device with fibronetin, Poly-L-lysine for facilitation of cell

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attachment. (Col. 3, line 30-32; Col. 6, line 27-37) Baumann et al. also teach using a fluorescence dye to monitor cell response. (Col.10, line 62-64) Although Baumann et al. do not explicitly teach using detergent or antibiotic to permeabilize cells, it is inherent in Baumann et al. teaching since Baumann et al. reference teaches measuring intracellular electrical response by applying voltage to the device. The voltage applied would inherently permeabilize tested cells in order to measure intracellular electrical current. With respect to dye Solvent Blue 14, it is a fluorescent dye, absence of particular function or purpose in choosing this fluorescent dye, it is inherently within the scope of ordinary skilled ones in the art.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4, 5, 14-18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Baumann et al. in view of Owen et al. (WO 99/66329).

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Baumann et al. reference has been discussed but does not explicitly teach second layer materials recited as in claim 4-5. Baumann et al. also do not specify particular cell type applicable for the cellular electrical measurement. Additionally, Baumann et al. do not specifically reveal the diameter of the pores. Owen et al. teach a high throughput screen method by using an apparatus comprising a biological membrane and a porous substrate to measure the electrical potential on the K⁺, Na⁺, Ca⁺⁺ ion channel proteins, e.g. transfected with cDNA construct encoding the proteins on variety of cells, including primary neuronal tissue, or epithelial or endothelial cells. (Abstract, claims 3-7, page 41) Owen et al. also teach adding materials to the layer for high resistance such as polyethylene, polytetrafluoroethylene. (Claims 10-12, 33) The pores of Owen et al are around 1-7 micron diameter. (Claims 16-17) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Baumann et al. with the different features as taught by Owen et al. because the need of high resistance seal to substrates to detect intracellular electrical conditions are routine practiced in the electrophysiology art.

8. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baummane et al. in view of Goldberg et al. (US 4961954)

Baummane et al. reference has been discussed but does not explicitly teach using materials to inhibit cell attachment. Goldberg et al. teach using silicone to reduce cell adhesion based on increase hydrophilicity on the surface. (Col. 2, line 45-50) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Baummane et al. with the method of reducing cell attachment as taught by Goldberg et al. to reduce the non-specific cell attachment on the surface.

9. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baummane et al. in view of Zavisian et al. (US 5995867).

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Baumann et al. reference has been discussed but does not explicitly teach using microscope-assisted photo-ablation to remove the second layer. Zavisian et al. teach using confocal microscope assisted laser beam to remove unwanted plaque tissues. (Figure 1; Col. 8, line 1-10) Microscope-assisted photo-ablation laser provides the advantages of localized treatment, more precision and reducing damages to target tissues. (Col. 2, line 5-40) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Baumann et al. with the confocal microscope assisted laser to remove the areas of layer contact the cellular attachment sites as taught by Zavisian et al. ^{to} minimize damages to the cell membrane and increase the accessibility for electrical conductance.

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baumann et al. in view of Iwata et al. (Int'l J. Biological Macromolecules 1999 25: 169-176)

Baumann et al. reference has been discussed but does not explicitly teach using enzymatic degradation to remove the polymer materials of second support layer from the biostructure. Iwata et al. teach an effective and efficient way of using depolymerase from *A. facalis* T1 bacteria to remove unwanted polymers in preparation of samples. (page 170, second and third paragraph) Iwata et al. indicates that enzymatic degradation of polymer units provides the advantages of increasing the mobility of polymer chains, and targeting the chain-packing regions. (page 170, second paragraph) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Baumann et al. with the enzymatic degradation of the unwanted polymers as taught by Iwata et al., since it is known and as a routine practice in the art.

Conclusion

11. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

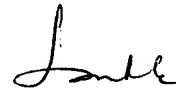
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
Art Unit 1641



November 20, 2003



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11/26/03